K130534

EMERGO GROUP

5. 510(K) SUMMARY

OCT 30 2013

Submission Correspondent

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Submission Date:	February 11, 2013
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Submission Sponsor

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Device Classification

Device Sponsor:	DIPLOMAT DENTAL, s.r.o.
Product Classification Name:	Unit, Operative Dental
Product Code:	EIA
Regulation Number:	872.6640
Classification Panel:	Dental Devices
Regulatory Class:	Class I

EMERGO GROUP

DIPLOMAT
DENTAL SOLUTIONS

Predicate Device

Sirona C8+Dental Operative Unit (K032543)

Statement of Intended Use

Diplomat dental operative units are self-contained dental treatment units that contain vacuum system and water supply and separate compressor placed outside the dental unit. These dental operative units are designed to provide air, water, vacuum and electricity to operate various dental hand-pieces, accessories and attachments, and to serve as a base for other dental devices and accessories. Diplomat dental operative units are offered with or without attached dental chairs. When supplied with a dental chair, the chair is intended to properly position a patient to perform different dental procedures. Diplomat dental operative units are to be operated and used by dentists and other legally qualified professionals, and are intended for use to provide general dental restorative care and hygiene procedures in both traditional dental office settings applications by or under the supervision of a licensed dentist or a hygienist if permitted by applicable law.

Device Description

Diplomat dental operative units are modern, ergonomically designed, dental systems offered in a wide range of models depending on the specific end user requirements. Diplomat dental operative units are AC-powered devices that are intended to supply power to, and serve as a base for, other dental devices and accessories – such as hand-pieces, operating lights, curing lights, ultrasonic instruments, hygiene instruments, etc. – and deliver electric, air, water and vacuum power to them. Diplomat dental operative units are offered either with the patient dental chair or as a free-standing unit without the chair for those end-users with existing patient chairs that they want to use. Diplomat dental operative units are offered in the following models and with the following accessories:

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Diplomat Dental Operative Units:

Adept DA 380, Adept DA 370, Adept DA 170, Adept DA 130, Adept DA 110A, Consul DC 350, Consul DC 310, Consul DC 180, Diplomat Consul DC 170, Diplomat Consul DC 170 (Orthodontic), Diplomat Lux DL 320; Diplomat Lux DL 210

Diplomat Dental Accessories:

Dental Chair DE 20, Dental Chair DM 20, Dental Stools D 10L, Dental Light Xenos, Dental Light Sirius

Predicate Device Comparison

Diplomat dental operative units by DIPLOMAT DENTAL have been shown to be Substantially Equivalent to the C8+Dental Operative Units manufactured by Sirona Dental Systems previously cleared by the FDA under K032543. The applicant and predicate devices are very similar in overall design and technology; principle of operation, intended use, materials, construction, and available accessories offered for them. The differences between the applicant and predicate devices do not raise any new questions of safety or effectiveness. Some select properties and characteristics of the applicant and predicate devices are compared side-by-side in the table below.

Features	Diplomat Dental Operative Units	C8+Dental Operative Unit	Substantially Equivalent
510(k)	Pending	K032543	-
Models	Adept Models: DA 380, DA 370, DA 170, DA 130, DA 110; Consul Models: DC 350, DC 310, DC 180, DC 170 and DC orthodontic; and Lux Models: DL 320, and DL 210	Multiple versions	Similar
Product Code	EIA	EIA	Same
Regulation Number	872.6640	872.6640	Same
Regulation Name	Unit, Operative, Dental	Unit, Operative, Dental	Same
Place of Use	Dental clinic	Dental clinic	Same
Intended Users	Dentists; assistants and hygienists	Dentists; assistants and hygienists	Same
Power Supply	110V/(230 VAC) 50/60 Hz	110V/115V/127V/(230 VAC) 50/60 Hz	Similar
Utility Supply	Compressed air and water	Compressed air and water	Same

Protection Class	Class 1 equipment	Class 1 equipment	Same
Degree of	Type B of applied parts	Type B of applied parts	Same
Protection			
Installation	Professionally installed; available with chair and cart mounted options.	Professionally installed; not available with chair and cart mounted options.	Same
Air Pressure	450 kPa/800 kPa (min./max.)	550 kPa/750 kPa (min./max.)	Similar
Water Pressure	300 kPa/600 kPa (min./max.)	250 kPa/600 kPa (min./max.)	Similar
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	EN 60601-1-2	IEC 60601-1-2	Similar
Performance	ISO 7494-1	-	-
Statement of Intended Use	Diplomat dental operative units are self-contained dental treatment units that contain vacuum system and water supply and separate compressor placed outside the dental unit. These dental operative units are designed to provide air, water, vacuum and electricity to operate various dental hand-pieces, accessories and attachments, and to serve as a base for other dental devices and accessories. Diplomat dental operative units are offered by with or without attached dental chairs. When supplied with a dental chair, the chair is intended to properly position a patient to perform different dental procedures. Diplomat dental operative units are to be operated and used by dentists and other legally qualified professionals, and are intended for use to provide general dental restorative care and hygiene procedures in both traditional dental office settings applications by or under the supervision of a	The C8 + Dental Operative Unit with accessories are intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair. The unit is intended for use in the dental clinic environment and used by trained dentists and/or dental technicians and assistants. The C8 + Dental Operative Unit is offered wilt the optional Sivision 3, an intraoral camera system intended to provide the dentist and patient with intraoral video images to view the condition of the teeth and oral cavity.	Similar

	of a licensed dentist or a hygienist if permitted by applicable law.		

Non-Clinical Data – Device Bench Testing

As part of demonstrating the safety and effectiveness of its line of Diplomat dental operative units, DIPLOMAT DENTAL has submitted these devices for performance testing in accordance with the applicable sections of the following international standards and FDA guidance documents:

- IEC 60601-1:2005, *Medical electrical equipment - Part 1, General requirements for basic safety and essential performance*
- EN 60601-1-2:2007, *Medical electrical equipment – Part 1-2, General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
- EN 60601-1:2009, *Medical electrical equipment - Part 1, General requirements for basic safety and essential performance*
- ISO 7494-1:2004, *Dentistry - Dental Units - Part 1: General requirements and test methods*

Clinical Data

Not applicable to this 510(k) submission.

Substantially Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and

that the new device does not raise new questions regarding its safety and effectiveness when compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Diplomat dental operative units by DIPLOMAT DENTAL when compared to the Sirona Dental Systems C8+Dental Operative Units (K032543) are minimal and do not raise any questions regarding their safety and effectiveness. Diplomat dental operative units, as designed and manufactured are therefore determined to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2013

Diplomat Dental, S.R.O.
C/O Mr. Stuart R. Goldman
Senior Consultant
Emergo Group, Incorporated
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K130534
Trade/Device Name: Dental Operative Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: September 23, 2013
Received: September 24, 2013

Dear Mr. Goldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Brimer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Devices Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) NUMBER (IF KNOWN): K130534

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Prescription Use X	AND/OR	Over-The-Counter Use _
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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